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Perpetually Liable? What the California Supreme Court Decision Means for Innovator Pharmaceutical Companies

The California Supreme Court ruling in *T.H. v. Novartis* expands the liability innovator pharmaceutical companies may face in California courts, attorneys Andrew L. Bab, Maura K. Monaghan, Paul D. Rubin, and Jacob W. Stahl say. The authors say the ruling creates the possibility that innovator pharmaceutical companies may face ''liability in perpetuity—even after they have stopped manufacturing a drug or sold all of its rights.''

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The December 2017 California Supreme Court's decision in *T.H. v. Novartis* (No. S233898) expands the liability innovator pharmaceutical companies may face in California courts.

The decision may permit a plaintiff to bring a failure to warn product liability claim against an innovator pharmaceutical company even though the company did not manufacture the drug ingested by the plaintiff, no longer sells the drug, and no long owns any rights to the drug. The decision creates the possibility that innovator pharmaceutical companies may face liability in perpetuity – even after they have stopped manufacturing a drug or sold all of its rights.

Such innovators may face a challenging situation because they do not have the ability to change the label of the drugs they formerly sold. The scope of this liability may depend both on decisions made by innovators and on the potential efforts by the Food and Drug Administration (''FDA'') to authorize the updating of certain generic drug labels. Although there are no sure-fire solutions to this problem, there are steps that innovator companies can take to mitigate the risks they may confront.

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T.H. and the Caselaw Expanding Innovator Liability

Until 2001, Novartis manufactured the prescription drug Brethine, an asthma drug that is sometimes prescribed off label to prevent preterm labor. Novartis then sold all rights to the drug to aaiPharma. aaiPharma subsequently manufactured and marketed the drug using the label that Novartis had drafted and used. In 2007, plaintiffs' mother ingested a generic version of the drug (terbutaline) during pregnancy to prevent premature labor. Her twin children—the plaintiffs—allegedly suffered significant harm as a result. Based upon U.S. Supreme Court precedent discussed below, the plaintiffs were unable to bring an action against the generic drug company that manufactured the drug their mother ingested. Instead, the plaintiffs sued Novartis, alleging that Novartis should have changed the drug's label in 2001 based on information then known to the company. Novartis filed a motion seeking to dismiss the case on the basis that it owed no duty to plaintiffs because, at the time the mother ingested the drug, Novartis no longer had any rights to the drug and was not manufacturing it. The California Supreme Court disagreed, holding that Novartis potentially could be held liable under a failure to warn theory based on what it allegedly knew in 2001.

The court's decision was based on its determination that the plaintiffs had adequately pled that it was foreseeable that aaiPharma would not change the label of the drug that it had purchased from Novartis. The court reasoned that aaiPharma was unlikely to change the label because adding to the label a warning that the drug posed risks to fetal development could jeopardize a significant portion of the drug's sales. The court reached

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this conclusion notwithstanding the typical presumption that parties will not act unlawfully.

T.H. represents the culmination of a series of state and federal court decisions that may – at least in California – leave innovator pharmaceutical companies the exclusive target of failure to warn claims regarding drugs they invent and for which they develop the label, regardless of whether the innovator actually manufactured the drug ingested by the plaintiff.

This trend began with the 2008 California appellate court decision in *Conte v. Wyeth*, which held that an innovator pharmaceutical company could be liable under a failure to warn theory even though the plaintiff took a generic version of the drug. That decision was also predicated on foreseeability: it was foreseeable, according to the court, both that prescriptions for an innovator drug would be filled with a generic version and that the plaintiff's doctor would prescribe the generic drug in reliance on the innovator's label.

The following year, the United States Supreme Court in *Wyeth v. Levine* permitted failure to warn claims against innovators – rejecting the argument that they were precluded by the preemption doctrine. In that case, the plaintiff alleged that she was injured as a result of being administered a drug manufactured by Wyeth (an innovator). She brought a failure to warn claim against Wyeth alleging that the drug's label was inadequate because it failed to provide proper instructions regarding how the drug should be administered. Wyeth sought to dismiss the complaint under two preemption theories: (i) that it would be impossible to comply with a state law duty to modify the drug's labeling without violating federal law and (ii) that the plaintiff's state law claims would interfere with the FDA's administration of the Federal Food, Drug, and Cosmetic Act. The Supreme Court disagreed because the FDA's ''changes being effected'' (''CBE'') regulations, addressed below, permit a manufacturer to add safety information to a label in advance of FDA's approval of that label. The Supreme Court also disagreed that the FDA's administration of its statutory authority would be frustrated, because prior to 2006, the FDA had repeatedly stated that it did not believe that state law claims would frustrate its mission.

In 2011, the Supreme Court in *PLIVA v. Mensing* held that failure to warn claims against generics *are* preempted by federal law notwithstanding that such claims against innovators are not preempted. The plaintiffs brought failure to warn claims against generic manufacturers. They argued that the defendants could have used the FDA's CBE process to change the label. The FDA disagreed, holding that under FDA regulations, a generic drug manufacturer must copy the label prepared by the innovator. The plaintiffs' claims were preempted because the duties imposed on the defendant under state law were incompatible with federal law.

As a result of *PLIVA*, plaintiffs who claim to be injured by a generic drug cannot sue the generic manufacturer. They can sue the innovator, but only in states like California that allow such suits. The *T.H.* decision goes a major step further. It allows a California plaintiff who ingested a generic drug to sue the innovator that designed the label, notwithstanding that the innovator sold the rights to its drug years earlier to another innovator drug company. Thus, in California an innovator may face failure to warn claims long after it ceases manufacturing a drug that it developed and even though it no longer has links to either the branded or generic version of the drug.

The vast majority of states have rejected the type of innovator liability adopted by the California courts. In Alabama, for example, after the state supreme court issued a decision similar to *Conte*, the state legislature overturned that decision. A number of other states have product liability statutes that have been interpreted to preclude suits against innovators by plaintiffs who ingested the generic version of the drug because they allow plaintiffs to sue only the entity that actually manufactured, distributed or sold the product that is alleged to have caused harm. Federal appellate decisions have similarly recognized an ''overwhelming national consensus'' that innovators cannot be sued for harm for injuries caused by ingesting generic products. However, because California is the nation's largest state, innovators unfortunately must address the risks posed by *Conte* and now *T.H.*

Who is responsible for updating the label of approved prescription drugs to add new warnings to the label? FDA regulations provide that if an innovator pharmaceutical company learns about a serious risk that is not reflected on the drug's label, then the innovator is obligated to update the label accordingly. Such changes may result in (i) adding or strengthening a contraindication, warning, precaution or adverse reaction; (ii) adding or strengthening a statement about drug abuse or dependence, psychological effect, or overdosage; (iii) adding or strengthening an instruction about dosage and administration that is intended to make the drug safer to use; or (iv) deleting false, misleading or unsupported statements on the label.

An innovator is obligated to update the label to reflect such risks so long as it maintains a New Drug Application (''NDA'') with the FDA, regardless of whether it is continuing to manufacture the drug. Changes to innovator drug labels to add or update warnings are typically implemented through the filing of an NDA Supplement. These are generally implemented through the CBE process. Under this process, the innovator generally must notify the FDA at least 30 days before any changes to the label are made. Affirmative FDA approval is generally not required, but the FDA can object to the proposed labeling change or request other changes.

The FDA may also require an innovator to change the label. Such a requirement might result from the FDA's surveillance of safety data, including adverse event reporting, the results of FDA inspections, medical literature and communications from foreign regulatory authorities. It could also result from a new FDA assessment of the risks or benefits of using a drug or the use of a drug in a particular population group. Based on such an analysis, FDA may require the types of changes to the label described above.

For generic drug manufacturers, the situation is complex. If they are manufacturing a drug for which there is an NDA on file with the FDA, the generic typically must follow verbatim the label of the NDA-approved drug. The FDA under the Obama Administration issued a proposed rule (known as the ''generic drug labeling rule'') that would have allowed generics to alter drug labeling to add safety warnings. The generic industry strongly opposed this proposal because, among other things, it could lead to an explosion of litigation against

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the generic industry. They argued that *PLIVA* was predicated on the requirement that generics follow the label for the innovator drug. If generics had the flexibility to change the label themselves, then the logic of *PLIVA* would no longer apply and generics would become subject to failure to warn claims. The FDA's proposed rule has never been finalized because of strong opposition from the generic industry and other stakeholders.

However, a generic does have labeling obligations when an NDA has been withdrawn for reasons unrelated to safety or efficacy. Innovators sometimes withdraw NDAs when they no longer wish to manufacture the drug at issue and do not sell rights to the drug to another entity. If the innovator's NDA is withdrawn, there is no longer any innovator ''reference listed drug.'' An FDA official indicated that there are currently more than 450 generic drug products for which there is no innovator marketing the product. In such circumstances, the generic company may be obligated to update the label for reasons such as achieving consistency with similar drugs, correcting outdated information, or following recent FDA labeling guidance. Generics may also be required to provide new warnings on drug labels regarding safety risks. Changes made under these circumstances must be implemented via the filing of an NDA Supplement.

FDA may now be embarking on a new initiative that would result in updated generic labels. The FDA's 2018 strategic plan states that it is launching a ''new pilot initiative to create a structure enabling the FDA to have its own capacity to more routinely update old generic drug labels with new safety and efficacy information.'' The FDA has not yet announced the details of its pilot initiative. However, the FDA may be trying to develop an FDA-directed process for updating generic labels without creating the avalanche of litigation targeting generic drug companies expected to result from the generic drug labeling rule. Under *PLIVA*, as long as labeling changes cannot be made without advance FDA approval, failure to warn claims will likely remain preempted.

What does T.H. mean for innovators who sold their rights to a drug or otherwise stopped manufacturing it? Innovators who have stopped manufacturing certain drugs (including due to a sale of rights) might consider whether they now face potential liability in light of *T.H.* The risk of a lawsuit is likely to be greatest if the innovator has sold it to another company that has limited resources. In those circumstances, plaintiffs are likely to look at the innovator as an attractive ''deep pocket.''

Innovators might consider conducting retrospective reviews of drugs that are most likely to face litigation exposure in light of *T.H.* Such reviews should be done under the supervision of counsel so that any findings are more likely to be protected from discovery by attorney-client privilege. A review should include determining what information was known to the company before it sold the drug or withdrew the NDA. Additionally, while review of later data should be unnecessary under the rationale relied on by the *T.H.* court, it may be difficult to segregate information known to the company before sale/withdrawal and information that emerged only later. For example, an innovator may have been aware of limited information about a potential risk at the time that it stopped manufacturing the drug, but the full extent of the risk became clear only later. Indeed, that may be the case in *T.H.*, as the court recognized that half of the studies cited in the complaint post-dated Novartis' sale of the rights to the drug. From a risk-mitigation perspective, therefore, it may be prudent for an innovator to consider data both before and after rights to the drug were sold or the NDA was withdrawn.

What should an innovator do if a retrospective review identifies information that could be fodder for a failure to warn claim? If the company has sold the drug or withdrawn the NDA, then the company no longer has the ability to change the drug's label. Determining what to do next requires a complex inquiry that should involve input from litigation and regulatory counsel.

If the company concludes that the risk is sufficiently high, then it may want to consider the possibility of notifying the successor company that now owns rights to the drug at issue (if there is one) or the FDA of its concerns. This might allow the company to argue in subsequent litigation that it had taken reasonable steps to raise awareness about the issue. Any such notification should be carefully drafted to maximize the likelihood that the court will view it as a subsequent remedial measure and not an admission of liability.

Ultimately, the FDA and a successor manufacturer (if there is one) would have to decide whether to change the label, because only they would have the legal authority and access to nonpublic information about the drug that is typically essential to deciding whether a labeling change is necessary. Such information is often confidential and would not be available to an entity that no longer manufactured the drug.

How should innovators structure future sales of drug rights in light of T.H.? *T.H.* creates a complicated dynamic for sales of innovator drug rights because innovators now face the risk that they could be subject to failure to warn claims years after the sale. Unlike in a typical transaction where the buyer conducts due diligence on the seller, here the seller may also want to conduct diligence on the buyer. In particular, the seller may want to investigate the buyer's financial worth and the buyer's attention to safety. An unspoken factor underlying the *T.H.* decision may have been that aaiPharma was a small company that went bankrupt less than two years before the events that led to this case. The court appears to have assumed that if a large, sophisticated company like Novartis was unwilling to change the drug's label, then a small company like aaiPharma certainly would not make any changes. If the buyer had been a larger, sophisticated pharmaceutical company that devoted significant resources to clinical safety issues, the result may have been different. Under those circumstances, the predecessor could have argued that it would be foreseeable that the buyer would carefully monitor safety data and would update the label as necessary. Indeed, the buyer would be far better positioned to make any post-sale decisions about labeling because the buyer – along with the FDA – would have the access to confidential data that provided a complete, up-to-date picture of the drug's safety and efficacy profile.

Once a buyer is identified, the most practical way for a seller to protect itself against *T.H.*-type litigation is to seek an indemnity. The scope of the indemnity (if any) would have to be negotiated because many buyers will

not want to provide open-ended indemnities. One option may be to establish an indemnity for a limited period of time. That should provide the seller with some comfort because with the passage of time, it may become more difficult (although not necessarily impossible) for plaintiffs to allege that their injuries resulted from decisions made many years earlier.

Innovators who are considering selling drugs should carefully monitor developments in the coming months and years that may shed more light on the likelihood that they will be subject to ongoing liability under the theory outlined in *T.H.* During that time, courts will elucidate whether *T.H.* is either (i) interpreted narrowly as a decision that arose on a motion to dismiss (when courts are often favorable to plaintiffs) and under the unique fact pattern of a subsequent drug company that went bankrupt or (ii) interpreted broadly as a mandate to open the floodgates to suits against predecessor innovators. The success of the FDA's planned efforts to update generic labels may also be significant. If the FDA begins taking an active role in updating generic labels when it believes that they are lacking critical safety information, it will become much harder for plaintiffs to argue that it was unforeseeable that a drug label would be updated after the sale of drug rights.

Does T.H. change an innovator's decision-making process with regard to whether it should keep manufacturing its drugs after there are generic competitors in the market? The interplay between *T.H.* and FDA labeling regulations incentivizes innovators to withdraw NDAs if and when generics take over the market and selling the innovator drug is no longer profitable. While withdrawing the NDA cannot extinguish liability for drug sales prior to the withdrawal, it may reduce the risk of liability going forward. At minimum, it is difficult for plaintiffs to base failure to warn claims on information that came to light only after the NDA was withdrawn and the innovator no longer has labeling responsibilities and is no longer receiving confidential safety data – with the caveat that plaintiffs might try to argue that post-NDA withdrawal information simply confirmed the relevance of pre-withdrawal information. Moreover, once an innovator withdraws its NDA, the generics have the ability – and potentially the responsibility – to change the label. Under such circumstances, the innovator could argue that *T.H.* is distinguishable, and the innovator should not be liable. The generic now has the ability to alter the label and therefore may itself be held liable in a failure to warn claim regarding a drug that it manufactured. From a policy perspective, one could argue that it makes sense for the generic – not the innovator – to be subject to liability in this context because the generic would be the only entity with authority over the drug's label and would be profiting from the drug's sales.

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